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TO: Honorable Commissioner of Patents and Trademarks  
Washington, DC 20231

ATTN: John Doll, Group Director  
Esther Kepplinger, Biotechnology Practice Specialist

FAX NO.: 1-703-305-3014

DATE: March 16, 1995

FROM: LAURA A. CORUZZI, ESQ.

PAGES: 28 (including cover page) OUR REF.: 7639-017

We are transmitting herewith:

PETITION UNDER 37 C.F.R. §§ 1.181, 1.182 AND/OR 1.183  
FOR THE GROUP DIRECTOR TO WITHDRAW THE OUTSTANDING  
OFFICE ACTION ERRONEOUSLY MAILED BY THE EXAMINER, AND  
TO DIRECT THE EXAMINER TO ISSUE A NOTICE OF  
ALLOWANCE AND GRANT APPLICANT'S REQUEST FOR INTERFERENCE

## FOR FILING IN:

## Application of:

ARTHUR SKOULTCHI

Serial No.: 08/102,390

Filed: August 5, 1993

For: PRODUCTION OF PROTEINS  
USING HOMOLOGOUS  
RECOMBINATIONSPECIAL STATUS GRANTED

Group Art Unit: 1804

Examiner: Ziska, S.

Atty Docket No.: 7639-017/  
Cell 3.2

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Date: March 16, 1995

PATENT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:

ARTHUR SKOULTCHI

**SPECIAL STATUS GRANTED**

Serial No.: 08/102,390

Group Art Unit: 1804

Filed: August 5, 1993

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ALLOWANCE AND GRANT APPLICANT'S REQUEST FOR INTERFERENCE

Honorable Commissioner of Patents and Trademarks  
Washington, D.C. 20231

Sir:

The above-captioned application has been granted special status,<sup>1</sup> and an expedited decision on this petition is respectfully and urgently requested. In order to assist the Group Director in reaching a decision, an interview is respectively requested.

The fee required for this petition is estimated to be \$130.00. Please charge the required fee to Pennie & Edmonds Deposit Account No. 16-1150. A duplicate of this sheet is enclosed for accounting purposes.

<sup>1</sup> Decision on Petition dated January 9, 1995, in response to Applicant's Petition To Make Special, filed December 29, 1994.

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LAURA A. CORUZZI

30,742  
(Reg. No.)

PENY2354952.1

TABLE OF CONTENTS

	<u>Page</u>
I. SUMMARY OF THE GROUNDS FOR THIS PETITION . . . . .	- 2 -
II. BACKGROUND . . . . .	- 4 -
III. STATEMENT OF FACTS . . . . .	- 7 -
A. The Examiner Has Acted Outside The Scope Of Her Authority . . . . .	- 7 -
B. The Claims Presented Are Patentable To The Applicant . . . . .	- 9 -
1. The Invention Is Not Obvious . . . . .	- 9 -
2. The Examiner's Rejection Of Certain Of The Claims Under 35 U.S.C. § 112 Regarding Entitlement To Priority Date Is Irrelevant To Any Issue Of Patentability In This Application . . . . .	- 11 -
3. The Claims Are Enabled And Definite . . . . .	- 14 -
C. An Interference Should Be Initiated . . . . .	- 15 -
IV. RELIEF REQUESTED . . . . .	- 16 -
A. The Group Director Should Withdraw The March 6th Office Action Because The Examiner Did Not Follow The PTO Requirement Set Forth In MPEP § 2307.02 . . . . .	- 18 -
B. The Group Director Has The Authority To Direct The Examiner To Allow The Claims Or Supply An Affidavit Under 37 C.F.R. § 107(b) . . . . .	- 19 -
C. The Examiner's Conduct Of The Prosecution Of This Application Is Contrary To The Policy Of The Patent Office For Conducting Examinations . . . . .	- 23 -
D. Failure To Withdraw The Examiner's Action And Progress The Application To A Declaration Of Interference Will Unduly Prejudice The Applicant . . . . .	- 25 -
V. CONCLUSION . . . . .	- 26 -

## PETITION

The claims pending in the present application define the same patentable invention (Rule 601(n)) as that of the claims of U.S. Patent No. 5,272,071 ("071 patent") granted to Chappel on December 21, 1993. The Applicant has requested, under 37 C.F.R. § 1.607, an interference with the '071 patent.<sup>2</sup>

Pursuant to the provisions of 37 C.F.R. §§ 1.181, 1.182 and/or 1.183,<sup>3</sup> the Applicant respectfully petitions for the Group Director:

- (a) to withdraw the March 6, 1995 Office Action erroneously issued by the Examiner in connection with the captioned application (hereinafter the "March 6th Office Action") pursuant to his authority under MPEP § 1003, item 6, because the Office Action was mailed without the approval of the Group Director as is required by MPEP § 2307.02; and
- (b) to review the record pursuant to his authority under MPEP § 1002.02(c)4, and direct the Examiner to:
  - (i) issue a Notice of Allowance and initiate an interference with the '071 patent; or, in the event this request is not granted,
  - (ii) suggest a claim that would define the same patentable invention as that of the '071 patent

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<sup>2</sup> Request Under 37 C.F.R. § 1.607 For Interference With A Patent filed by Applicant on June 1, 1994.

<sup>3</sup> Though, in all likelihood, the present Petition falls most appropriately under 37 C.F.R. § 1.181, the Applicant submits this Petition Under 37 C.F.R. §§1.181, 1.182 and/or 1.183 as appropriate grounds for this petition.

and that would be patentable to Applicant; or,  
in the event this request is not granted,  
(iii) to file an affidavit pursuant to 37 C.F.R.  
§ 1.107(b) providing evidence to support the  
Examiner's reasons for rejection of the claims.  
(MPEP § 706.02(a)).

This matter is appropriately submitted to, and  
should be decided by the Group Director (MPEP § 1002.02(c)4  
and § 1003, item 6).

I. SUMMARY OF THE GROUNDS FOR THIS PETITION

The basis for this petition is that the grounds of  
the prior art rejections of the pending claims are applicable  
to the claims of the '071 patent, and therefore, any letter  
including such rejections require approval of the Group  
Director. MPEP § 2307.02. The March 6th Office Action was  
prepared and mailed by the Examiner without approval by the  
Group Director; no signature appears on the Office Action  
other than that of the Examiner. Thus, the Examiner acted  
outside the scope of her authority, and erroneously issued the  
Office Action.

The Applicant respectfully requests that the Group  
Director exercise his authority and withdraw the Office  
Action, review the record and direct the Examiner to issue a  
Notice of Allowance and initiate an Interference with the '071  
patent. A Notice of Allowance should be issued because, as  
shown by the record, the art used by the Examiner to support  
the obviousness rejection under 35 U.S.C. § 103, is the very  
same art that the Applicant already addressed and has relied

on to support non-obviousness of the claimed invention, as set forth in Applicant's previous Amendment, which included a declaration under 37 C.F.R. § 1.132 by Dr. Michael Liskay, explained more fully below. Since the references relied on by both sides are the same, the different conclusions reached can only be due to different analyses and interpretations of the teachings of the art and what the teachings would have meant to one of ordinary skill in the art at the time of the invention. Here, the Examiner's analysis and opinion must give way to one truly skilled in the art who was active in the field, and "on the scene" at the time the invention was made. In re Zeidler, 682 F.2d 961, 215 U.S.P.Q. 490 (C.C.P.A. 1982).

In this regard, the Applicant filed a Declaration Under 37 C.F.R. § 1.132 of Dr. Michael Liskay -- an outside, unbiased investigator who is eminently qualified to evaluate the invention and the art -- indeed, Dr. Liskay is an author of one of the references that the Examiner had previously applied against the claims.<sup>4</sup> In his declaration, Dr. Liskay analyzes the factual underpinnings of the obviousness inquiry

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<sup>4</sup> A review of the record reveals that the Examiner has issued a series of Office Actions, each with a new ground or basis for rejection; setting up "straw man" arguments that the Applicant has consistently and forthrightly knocked down. In derogation of the mandate of the MPEP to cite the best art that can be applied against the claims in order to focus the prosecution and proceed in an expeditious manner (MPEP §§ 706 and 706.07), this Examiner has turned the prosecution into a game of shooting at a moving target, thus, prolonging the examination procedure and wasting precious time. Meanwhile, the patent rights which Applicant believes have been awarded to the wrong party are in the hands of a foreign corporation who can, and is, using them in derogation of the rightful owners of the subject invention. This is against the public interest, the policy behind the Rules of Practice, and the procedures set forth in the MPEP.

by putting into context what the articles relied on by the Examiner in the March 6th Office Action would or would not have meant to one of ordinary skill in the art at the time of the invention. Dr. Liskay explains why the art does not suggest the invention, and why one of ordinary skill in the art at the time of the invention would not have had a reasonable expectation of success. Dr. Liskay sets forth the facts in support of his analysis. A legal determination of non-obviousness must follow from Dr. Liskay's factual analysis. In re Vaeck, 947 F.2d 488, 20 U.S.P.Q.2d 488 (Fed. Cir. 1991). Ironically, one of the references relied on by the Examiner, i.e., Smithies et al., 1985, Nature 317:230-234, was supplied by Dr. Liskay to show failure in the art and no reasonable expectation of success -- i.e., the exact opposite of what is required for a finding of obviousness.

Since the Examiner's contrary determination of obviousness is based upon the same references evaluated by Dr. Liskay to support nonobviousness, her conclusions must be based upon (a) her own opinion unsupported by facts, in which case, the rejections should be withdrawn and a Notice of Allowance issued; or (b) facts within her personal knowledge, or that of another employee of the Patent Office, that allegedly support her application of the references, in which case, the Examiner should be required to file an affidavit in accordance with 37 C.F.R. § 1.107(b).

## II. BACKGROUND

The invention relates to the use of targeted homologous recombination for gene activation and/or greatly

enhancing the expression of endogenous target genes in mammalian host cells for purposes such as large scale protein production. The present application was filed on August 5, 1993 as a Rule 60 continuation of application Serial No. 07/787,390 filed on November 4, 1991 ("390 parent application"), as the national stage of International application PCT/US90/06436 filed November 6, 1990. The '390 application also claims priority under 35 U.S.C. § 120 as a continuation-in-part of U.S. application Serial No. 432,069 filed November 6, 1989 ("069 grandparent application").

In the first Office Action, dated March 14, 1994, the claims were rejected under 35 U.S.C. § 102(b) as anticipated by the International counterpart application of the '071 patent -- WO91/09955 published July 11, 1991. This rejection was withdrawn since the publication of WO91/09955 was subsequent to the effective date of the instant application.<sup>5</sup> On June 1, 1994, concurrently with its amendment in response to the first Office Action, the Applicant submitted a request under 37 C.F.R. § 1.607 for interference with the '071 patent.<sup>6</sup> The pending application claims the same patentable invention (Rule 601(n)) as that of

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<sup>5</sup> Second Office Action, dated September 21, 1994. The July 11, 1991 publication date of WO91/09955 is subsequent to both the November 6, 1989 U.S. filing date and the November 6, 1990 International filing date to which the instant application claims priority.

<sup>6</sup> In accordance with the Applicant's request, the Examiner scheduled an interview which was held on July 14, 1994. However, the Examiner was unprepared. She did not obtain the file in time to prepare for the scheduled interview, and did not notify the Applicant in time to cancel or reschedule.



the '071 patent, which issued from a series of applications, the earliest of which was filed December 22, 1989.

In a second Office Action, dated September 21, 1994, the Examiner acknowledged the request for interference, but indicated that an interference would not be declared until the instant application contains allowable claims. The Examiner withdrew her original rejections, but issued new rejections under 35 U.S.C. § 103 based on new art. This Office Action was reviewed and approved by the Group Director.<sup>7</sup> The Applicant interviewed with the Examiner, her Supervisor, Ms. Esther Kepplinger, the Group Director, Mr. Charles Warren and the Director, Mr. Barry Richman, on November 16, 1994.

The application was granted Special Status on January 9, 1995, in response to the Applicant's Petition filed December 29, 1994. An amendment, which was fully responsive to each ground of rejection was filed on February 7, 1995. This amendment reflected all of the points raised at the November Interview, including amendments to the claims made in accordance with suggestions of the Group Director, Mr. Charles Warren. As part of this response, the Applicant submitted a declaration under 37 C.F.R. § 1.132 of Dr. Michael Liskay -- an unbiased, outside investigator in the field -- to address the factual underpinnings of the Applicant's responses to all outstanding rejections. Dr. Liskay cited certain references to support the facts put forward in his declaration.

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<sup>7</sup> The art-based rejection in the second office action was applicable to the claims of the '071 patent. Therefore, the Group Director's approval was required. MPEP § 2307.02.

On March 6, 1995, the Examiner mailed a final Office Action withdrawing the rejections based on obviousness in view of the art, but fashioned a new obviousness rejection in view of the very same art relied on by the Applicant and cited by Dr. Liskay to show the unexpected nature and nonobviousness of the invention. This Office Action was issued in error.

### III. STATEMENT OF FACTS

The facts on which the Applicant predicates the instant petition, and which are substantiated in the record of this application, are set forth below.

#### A. The Examiner Has Acted Outside The Scope Of Her Authority

The instant application claims subject matter that defines the same patentable invention (Rule 601(n)) as that of the claims of the '071 patent, and the Applicant has requested the declaration of an interference. In such situations, the application should be "taken up at once and the examiner must determine whether the presented claims are patentable to the applicant." MPEP § 2307.02. This section of the MPEP further provides that any letter including a rejection of the pending claims which may be applicable to the claims in the patent, must have the approval of the group director.

In violation of the foregoing requirement of the MPEP, the Examiner has mailed the March 6th Office Action setting forth an art-based rejection of the pending claims that is applicable to the claims of the '071 patent, without the approval of the Group Director.

In particular, in the March 6th Office Action, the claims are rejected as obvious under 35 U.S.C. § 103 in view of the following combination of references;<sup>8</sup>

- (1) Thompson et al., 1989, Cell 56:313-321  
("Thompson");
- (2) Smithies et al., 1985, Nature 317:230-234  
("Smithies"); and
- (3) Nandi et al., 1988, Proc. Natl. Acad. Sci.  
85:3845-3849 ("Nandi").

Each of Thompson (published in January 1989), Smithies and Nandi was published prior to the earliest effective date which could possibly be accorded to the '071 patent (i.e., December 22, 1989). These references were not cited in the prosecution history of the '071 patent. Therefore, the rejections of the pending claims on the grounds of obviousness based on these references are applicable to the claims of the '071 patent. As a result, the March 6th Office Action required approval of the Group Director.

The March 6th Office Action, which was signed only by the Examiner, was neither reviewed nor approved by the Group Director as indicated by the absence of any referral to the Group Director, much less his signature.<sup>9</sup> This violates

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<sup>8</sup> The Office Action also combines these core references with other secondary references as a basis for rejecting the dependent claims.

<sup>9</sup> The Examiner is apparently aware of this requirement. In the previous Office Action dated September 21, 1994, where the rejection of the claims was likewise deemed to be applicable to the '071 patent, the then Group Director, Mr. Charles Warren, approved the action as indicated by his signature. The rejections set forth in the Second Office Action were withdrawn in response to the Applicant's amendment filed February 7, 1995.

the provisions of MPEP § 2307.06 and, therefore, the March 6th Office Action must be withdrawn.

B. The Claims Presented Are Patentable To The Applicant

Despite the length of the March 6th Office Action (over 40 pages long), in essence, there are only two grounds of rejection, obviousness under 35 U.S.C. § 103, and non-enablement and indefiniteness under 35 U.S.C. § 112.<sup>10</sup> Each is addressed briefly below.

1. The Invention Is Not Obvious

As shown by the record, the art now relied on by the Examiner to support her rejection for obviousness under 35 U.S.C. § 103, is the very same art the Applicant has relied on to support non-obviousness of the claimed invention.<sup>11</sup> In his declaration filed under 37 C.F.R. § 1.132, Dr. Liskay puts into context what the art relied on would or would not have meant to one of ordinary skill at the time of the invention. He analyzes the factual underpinnings of an obviousness inquiry -- why the art relied on does not suggest the invention and why one of ordinary skill in the art at the time of the invention would not have had a reasonable expectation of success. A legal determination of non-obviousness must follow from Dr. Liskay's factual analysis. In re Vaeck,

<sup>10</sup> Only Claim 27 and claims dependent therefrom are rejected under 35 U.S.C. § 112.

<sup>11</sup> Although Nandi was not specifically cited by the Applicants, Nandi relates to, and is an extension of the work in Smithies -- an article supplied by Dr. Liskay to show that there was no reasonable expectation of success in the field.

supra; In re Oelrich, 579 F.2d 86, 198 U.S.P.Q. 210 (C.C.P.A. 1978).

The Examiner's opinion based upon the very same references is opposite to the legal conclusion that should be drawn from the facts of record. Thus, the Examiner's rejection cannot stand. First, the Examiner is not one of ordinary skill in the art and whether she believes that the invention was obvious is legally irrelevant. The legal standard is what the references would suggest to one of ordinary skill in the art, and whether one of ordinary skill in the art would have reasonably expected success. In re Vaeck, supra. Second, the Examiner's analysis is contradicted by Dr. Liskay's declaration. Dr. Liskay is an unbiased researcher who is eminently qualified to set forth what was known and not known, expected and unexpected in this field at the time of the invention; a man of skill in the art, active in the field at the time the invention was made. The Examiner cannot substitute her judgment for that of a qualified expert. In re Zeidler, supra. Third, the Examiner has not set forth any facts to support her opinion that the art both suggested the claimed invention and would have provided one of ordinary skill in the art at the time of the invention with a reasonable expectation of success. The facts of record support the Applicant's legal conclusion that the claimed invention is not obvious. At a bare minimum, the Examiner should be required to come forward with an affidavit under 37 C.F.R. § 1.107(b) to support her reference, and in the absence of such an affidavit, withdraw the rejections based on obviousness.

Finally, the March 6th Office Action itself indicates that the Examiner is, in fact, engaging in an improper obviousness analysis since she is relying on hindsight reconstruction. In particular, on p. 42 of the March 6th Office Action, the Examiner utilizes the Applicant's discovery and teaching to support a finding that one of ordinary skill in the art would have had a reasonable expectation of success; i.e., the Applicant's recognition that in accordance with the invention, when problems are encountered in a particular cell type, targeted homologous recombination can be accomplished in a different target cell. It is clear error to use the Applicant's own teaching against the invention. In re Pine, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988) -- a practice which the Examiner has engaged in throughout the prosecution of this application.

2. The Examiner's Rejection Of Certain  
Of The Claims Under 35 U.S.C. § 112  
Regarding Entitlement To Priority Date  
Is Irrelevant To Any Issue Of  
Patentability In This Application

The Examiner has spent a good deal of time in this prosecution addressing the question of whether the claims, as they relate to the integration of promoters, are entitled to the benefit of the November 6, 1989 filing date of the '069 grandparent application. However, this question is irrelevant to any bona fide issue of patentability in this case. There is no intervening art applied against the claims,<sup>12</sup> and,

<sup>12</sup> In the first Office Action issued in connection with this application, the claims were rejected as anticipated by the foreign counterpart of the '071 patent, which published on July 11, 1991. This rejection was  
(continued...)

therefore, it is improper for the Examiner to consider this issue. MPEP § 201.15.

Despite the foregoing, and in view of the Examiner's vehemence on this point, the Applicant has addressed the issue solely to set the record straight, and to make it absolutely clear that he does not concede the point. This exercise has involved the "battle of the dictionaries" and textbooks to show the Examiner that the terminology used in the application, i.e., "transcriptional initiation region," means "promoter" according to its common, ordinary meaning. The Examiner accuses the Applicant of providing a 1981 definition that is "too old to be of value" in 1989 (March 6th Office Action, pp. 5-6); yet by that criterion, the definitions supplied by the Examiner are likewise ancient, as they were published only two years later in 1983. Again the Examiner ignores the analysis of Dr. Liskay -- a man certainly qualified to define a promoter, and who took into account all the definitions of record.

In the March 6th Office Action, page 3, the Examiner now rejects the claims under 35 U.S.C. § 112, for lack of "literal support" in the '069 grandparent application'. Applicant fails to see how a claim can be rejected under Section 112 based on what a parent specification states or does not state! All that is relevant to a Section 112

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<sup>12</sup>(...continued)

withdrawn. Even the Examiner admits that the claims are entitled at least to the benefit of the November 6, 1990 filing date of the International application PCT/US90/06436, which contains the entire disclosure of the '390 continuation-in-part application. However, the Applicant believes that the claims are clearly entitled to the November 6, 1989 filing date of the '069 grandparent application.

rejection is what the instant specification teaches or does not teach. The teachings of a parent application are only relevant to whether or not the pending claims are entitled to benefit under 35 U.S.C. §§ 119 or 120. Also, entitlement to benefit under Section 119 or 120 requires that a parent application meet the requirements of Section 112, first paragraph, not second paragraph as maintained by the Examiner. Entitlement to benefit of the November 6, 1989 filing date is not an issue in this case, because there is no intervening art. Therefore, this rejection is erroneous and irrelevant.

This has not deterred the Examiner from now requiring "literal support" for the term "promoter" in the '069 grandparent application. However, "literal support" is not required by the law. The proper test for sufficiency of support under 35 U.S.C. § 112, first paragraph, is whether the disclosure of the parent application reasonably conveys to the artisan that the inventor had possession, at that time, of the later claimed subject matter. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991); Ralston Purina Co. v. Far-Mar-Co., Inc., 772 F.2d 1570, 227 U.S.P.Q. 177 (Fed. Cir. 1985).

To add insult to injury, the Examiner, professing confusion, contorts the plain meaning of the specification and now contends that the '069 grandparent application only supports the integration of an exogenous gene along with its promoter. Once again, the Examiner's strained interpretation is wrong; as shown by her misinterpretation of a passage quoted from the '069 grandparent application in which the Examiner ignores the word "or" (e.g., see March 6th Office



Action at pp. 6 and 9). This is critical, because the use of the alternative in the cited passage indicates that the invention provides for at least two alternate embodiments; i.e., targeting an amplifiable gene within or proximal to the target gene, so that expression of the target gene is amplified but controlled by its wild type promoter; OR targeting a regulatory sequence within or proximal to the target gene so that the transcriptional regulation of the target gene expression is changed.

### 3. The Claims Are Enabled And Definite

Claim 27, and claims dependent therefrom, covering integrating an amplifiable gene within or proximal to the endogenous target gene so that the target gene is amplifiable are erroneously rejected under 35 U.S.C. § 112 as not enabled and vague. In particular, the Examiner contends that integration of the amplifiable gene proximal to or within the endogenous target gene is inconsistent with the claim limitation that the endogenous target coding sequence not be disrupted. This rejection is based on error and should be withdrawn.

As explained both at the interview on November 16, 1994 and in the previous amendment filed February 7, 1995, the amplifiable gene or the regulatory sequence can be inserted proximal to the target gene or within an intron of the target gene -- the insertion within an intron will not disrupt production of a proper mRNA transcript, and therefore, does not disrupt the coding sequence of the target gene product. (e.g., see p. 23 of the amendment filed February 7, 1995,

which explains this point and cites support in specification). In view of the foregoing, the claims are enabled and definite within the meaning of 35 U.S.C. § 112.

C. An Interference Should Be Initiated

Although the claims presented herein have been amended during prosecution to clarify claim language in response to rejections under 35 U.S.C. § 112, the subject matter of the claimed invention has never changed. Recognizing that the application and the '071 patent claim the same patentable invention (Rule 601(n)), the Applicant requested an interference with the '071 patent.

As reflected by the record, the Examiner also appreciates that the instant application and '071 patent claim the same invention. In particular, in the first Office Action dated March 24, 1994, the claims were rejected as anticipated by the foreign counterpart of the '071 patent -- International application WO91/09955, which published July 11, 1991. This rejection was withdrawn in response to the Applicant's amendment pointing out that WO91/09955 was an intermediate reference published subsequent to the earlier priority dates of the instant application; namely, the November 6, 1990 International filing date, and the November 6, 1989 U.S. filing date to which the present application claims benefit of priority under 35 U.S.C. § 120.<sup>13</sup>

<sup>13</sup> Assuming arguendo that the Examiner were correct that the claims were not entitled to the November 6, 1989 filing date for engineering promoters as the regulatory element, the result would be no different. The November 6, 1990 International priority date claimed under 35 U.S.C. § 119, is sufficient to antedate the July 11, 1991  
(continued...)

Since the present application is patentable to the Applicant, and claims the same patentable invention as that claimed in the '071 patent, the requested interference should be initiated.

#### IV. RELIEF REQUESTED

Under the circumstances, and pursuant to 37 C.F.R. §§ 1.181, 1.182 and/or 1.183,<sup>14</sup> and the authority set forth below, the Applicant respectfully petitions for the Group Director:

- (a) to withdraw the March 6th Office Action erroneously issued by the Examiner pursuant to his authority under MPEP § 1003, item 6, because the Office Action was mailed without the approval of the Group Director as is required by MPEP § 2307.02; and
- (b) to review the record pursuant to his authority under MPEP § 1002.02(c)4, and direct the Examiner to:
  - (i) issue a Notice of Allowance and initiate an interference with the '071 patent; or, in the event this request is not granted,
  - (ii) suggest a claim that would define the same patentable invention as that of the '071 patent

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<sup>13</sup>(...continued)

publication of the '071 foreign counterpart application. The disclosure of the International application is identical to that of the continuation-in-part application, filed November 4, 1991, which not only describes but also exemplifies the use of promoters.

<sup>14</sup> Though, in all likelihood, the present Petition falls most appropriately under 37 C.F.R. § 1.181, the Applicant submits this Petition Under 37 C.F.R. §§1.181, 1.182 and/or 1.183 as appropriate grounds for this petition.

and that would be patentable to Applicant; or,  
in the event this request is not granted,  
(iii) to file an affidavit pursuant to 37 C.F.R.  
§ 1.107(b) providing evidence to support her  
reasons for rejection of the claims.  
(MPEP § 706.02(a)).

This matter is appropriately submitted to, and  
should be decided by the Group Director (MPEP § 1002.02(c)4  
and § 1003, item 6).

These requests should be granted because: (1) the  
Examiner erred procedurally and acted outside the scope of her  
authority by mailing the March 6th Office Action that includes  
a rejection that is applicable to the claims of the '071  
patent; (2) the invention is patentable to the Applicant in  
view of the facts of record, including the declaration under  
37 C.F.R. § 1.132 of Dr. Liskay, that is not based on pure  
opinion, but sets forth the facts that support Applicant's  
position, and therefore, is formally sufficient and proper;  
(3) the pending claims cover the same patentable invention as  
that claimed in the '071 patent; and (4) the Examiner's  
handling of the prosecution of this application violates the  
public policy underlying the rules of examination as set forth  
in the Code of Federal Regulations and the MPEP, and as a  
result, has prejudiced the Applicant's valuable patent rights  
to its invention.

- A. The Group Director Should Withdraw The March 6th Office Action Because The Examiner Did Not Follow The PTO Requirement Set Forth In MPEP § 2307.02

The Applicant relies on the written policies of the PTO set forth in the Code of Federal Regulations and the MPEP,<sup>15</sup> which set forth the guiding principles that the PTO ostensibly follows in examining applications.

The MPEP, in a section aptly entitled "Rejection of Claims Corresponding to Patent Claims" prescribes:

When claims corresponding to claims of a patent are presented, the application is taken up at once and the examiner must determine whether the presented claims are patentable to the applicant. If they are not, they should be rejected on the appropriate ground(s). MPEP § 2307.02.

In connection with the rejection of pending claims corresponding to claims of a patent, this section of the MPEP further provides, "[t]he ground of rejection of the [pending] claims may or may not also be applicable to the claims in the patent; if it is, any letter including the rejection must have the approval of the Group Director," citing MPEP § 1003, item 6, for the Group Director's authority. The proscription set forth in the MPEP ensures that primary examiners do not, without authority or review, denigrate patents issued by the Office. This rule also ensures consistent results in the Patent Office examination proceedings.

<sup>15</sup> In Ethicon Inc. v. Quigg, 849 F.2d 1422, 1425, 7 U.S.P.Q.2d 1152, 1154 (Fed. Cir. 1988), the Court stated, "[t]he MPEP states that it is a reference work on patent practices and procedures and does not have the force of law, but it has been held to describe the procedures on which the public can rely" (citing Patlex, 758 F.2d at 606, 225 U.S.P.Q. at 252; emphasis supplied).

This directive was clearly not followed by the Examiner of the present application. Apparently, acting as a "lone-wolf" outside the scope of her authority, the Examiner mailed the March 6th Office Action rejecting the pending claims as obvious over art which *is not of record* in the '071 patent, and which *antedates the earliest effective date* that could possibly be accorded to the '071 patent. Therefore, in violation of MPEP 2307.02, the Examiner issued a letter including a rejection that is applicable to the claims of the '071 patent, without approval of the Group Director.

In view of the foregoing, the Group Director should withdraw the March 6th Office Action.

B. The Group Director Has The Authority  
To Direct The Examiner To Allow The Claims Or  
Supply An Affidavit Under 37 C.F.R. § 107(b)

The MPEP provides that petitions invoking the supervisory authority of the Commissioner under 37 C.F.R. § 1.181 involving any ex parte action or requirement in a patent application by an examiner which is not subject to an appeal are to be decided by the Group Director. MPEP § 1002.02(c). This section of the MPEP offers the following examples of petitions to be decided by the Group Director:

- (e) relative to formal sufficiency and propriety of affidavits under . . . 37 C.F.R. § 1.132 (MPEP § 716); and
- (f) refusal to initiate an interference under 37 C.F.R. § 1.601(i), MPEP § 2306.

In the present instance, the Group Director is requested to review the record, determine the formal

sufficiency and propriety of the declaration by Dr. Liskay, and review the Examiner's refusal to initiate the interference requested. Pursuant to his authority specified above, the Group Director should direct the Examiner to properly evaluate the record, including the factual evidence proffered under 37 C.F.R. § 1.132, allow the claims and initiate the interference with the '071 patent; or in the alternative, to propose a claim that would define the same invention as the '071 patent and which would be allowable to the Applicant; or in the further alternative, to supply an affidavit by the Examiner pursuant to 37 C.F.R. § 1.107(b), specifically stating the facts known *only* to the Examiner which support her application of the references to the claims.

The evidence of record clearly shows that the claimed invention is not obvious and should be patentable to the Applicant, and that the application covers the same invention claimed in the '701 patent. Therefore, a notice of allowance and declaration of interference should be issued.

The sole issue involved is obviousness under 35 U.S.C. § 103.<sup>16</sup> However, the propriety of the Examiner's basis for rejection is questioned. Ironically, to support her obviousness rejection, the Examiner relies on the very same references relied on by the Applicant to show nonobviousness of the claimed invention. Since the references speak for

<sup>16</sup> Certain of the claims are also rejected as indefinite and denied benefit of the earliest priority date under 35 U.S.C. § 112. The indefiniteness rejection, which applies to only some of the claims, and the denial of the earliest priority date are irrelevant to issues of the patentability of at least one claim corresponding to the claims of the '701 patent, which is all that is required to provoke an interference. MPEP § 2307.02 Squires v. Corbett, 194 U.S.P.Q. 513 (CCPA 1977).

themselves, and say what they say, the only basis for the rejection lies in the interpretation of the references and what their disclosures would or would not have meant to the ordinarily skilled artisan at the time of the invention.

In this regard, the Applicant supplied the declaration of an unbiased outside expert, Dr. Liskay, who placed the cited art in context, and set forth the factual underpinnings of an obviousness analysis -- why the cited art does not suggest the invention, and why the art would not have provided one ordinarily skilled at the time of the invention with a reasonable expectation of success. Indeed, Dr. Liskay cites additional articles to support his analysis of the cited art and to provide evidence of the state of the art at the time of the invention. The only legal conclusion which can be drawn based on these facts adduced by the Applicant, is that the invention is not obvious. In re Vaeck, supra.

There is no question that Dr. Liskay is eminently qualified in the field of the invention -- the Examiner herself cited his work against the claims in a previous Office Action. The Examiner cannot substitute her judgment for that of a qualified expert. In re Zeidler, supra. The only rebuttal that the Examiner has now mustered is to totally ignore the facts set forth in Dr. Liskay's declaration, dismissing it as pure opinion -- it is not. Even a cursory review of Dr. Liskay's declaration by the Group Director under the authority vested in him pursuant to MPEP § 1002.02(c)4(e) will reveal that each of Dr. Liskay's statements is supported by facts of record, or facts which he made of record, that are pertinent to the Examiner's rejection. Therefore, the



declaration is not based on pure opinion and is sufficient as to form and properly presented. In re Oelrich, supra; MPEP §§ 1002.02(c)4(e), and 716 at p. 700-84, first column, subparagraph (2).

When pitted against the facts set forth in Dr. Liskay's declaration, the Examiner's rejection must fail. Therefore, the Group Director is requested to require the Examiner to allow the claims and initiate the interference.<sup>17</sup>

Should the Examiner attempt to deny patentability to the Applicant e.g., on the grounds of 35 U.S.C. § 112, then the Group Director is requested under his authority specified in MPEP § 1002.02(c)4(f) to instruct the Examiner to suggest a claim to the Applicant which would define the same patentable invention as the '071 patent, and which would be patentable to the Applicant pursuant to MPEP § 2306.

In the event that the Examiner persists in her rejection of the claims as obvious under 35 U.S.C. § 103, and since the rejection would have to be based on her pure unsupported opinion or facts which are within her personal knowledge, the Group Director is requested to require the Examiner to supply an appropriate declaration under 37 C.F.R. § 1.107(b) setting forth specific facts and data which allegedly support the application of the references against the claims. This declaration should specifically state facts known to the Examiner which evidence the knowledge of one

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<sup>17</sup> There is no question that even the Examiner recognizes that the pending claims correspond to the claims of the '071 patent. In her first Office Action, the Examiner initially rejected the claims as anticipated under 35 U.S.C. § 102(b) by the foreign counterpart of the '071 patent -- a rejection which was withdrawn in view of the Applicant's earlier claim to priority.

skilled in the art at the time, and how such a person would have interpreted the references.

C. The Examiner's Conduct Of The Prosecution Of This Application Is Contrary To The Policy Of The Patent Office For Conducting Examinations

The record indicates that the Examiner has either chosen to ignore, or lost site of her role in the prosecution of this application so as to advance the prosecution to a speedy resolution, yet at the same time deal justly with both the Applicant and the public. MPEP § 706.07. As aptly stated in the MPEP section dealing with rejections in the chapter on Examination of Applications, "[a]lthough this part of the Manual explains the procedure in rejecting claims, the examiner should never overlook the importance of his or her role in allowing claims which properly define the invention." MPEP § 706.

A review of the record reveals that the Examiner has engaged in a game of "bait-and-switch." In each Office Action, the previous rejection was withdrawn and replaced with a new ground or basis for rejection; switching from one set of references to another. Ostensibly, according to the Examiner, each new ground of rejection was necessitated by the amendments to the claims. However, a careful review of the record also reveals that the invention covered by the claims in this application never changed despite amendments which were made to satisfy the Examiner's rejections under 35 U.S.C. § 112. The Examiner's record in this case is contrary to the examination procedure mandated by the MPEP, which states in pertinent part, at § 706.07:

Before final rejection is in order a clear issue should be developed between the examiner and applicant. To bring the prosecution to as speedy conclusion as possible and at the same time to deal justly by both the applicant and the public, the invention as disclosed and claimed should be thoroughly searched in the first action and the references fully applied; and in response to this action the applicant should amend with a view to avoiding all grounds of rejection and objection. Switching from one subject matter to another in the claims presented by applicant in successive amendments, or from one set of references to another by the examiner in rejecting in successive office actions claims of substantially the same subject matter, will alike tend to defeat attaining the goal of reaching a clearly defined issue for early determination; i.e., either an allowance of the case or a final rejection." (emphasis supplied).

That the Examiner has not followed the foregoing mandate of examination procedure is underscored not only by the record, but by her own words uttered at the November 1994 Interview, attended by her Supervisor, the Group Director and the Director, who did not condone her approach. At the Interview, the Examiner explained that first, she rejects the claims; then the Applicant amends the claims; then, the Examiner conducts another search of the art in order to find additional art to apply against the amended claims. Her procedure reflects a unique approach to patent examination that is not condoned by the MPEP, and serves only to prolong the pendency of applications, resulting in severe prejudice to Applicant's valuable patent rights.

D. Failure To Withdraw The Examiner's  
Action And Progress The Application To  
A Declaration Of Interference Will  
Unduly Prejudice The Applicant

The Applicant believes that he is the first and true inventor of the subject matter claimed in the instant application; however, the patent, was granted to another who actually filed his application subsequent to the present application -- the applicant of the '071 patent. Seeking to correct this error, the Applicant has earnestly sought to obtain allowance of his claims and provoke an interference with the '071 patent, in order to resolve the issue of who first invented the claimed subject matter, and thus, is entitled to the patent.

However, due to the Examiner's dilatory tactics, refusal to meet the issues of patentability head-on, and refusal to fairly consider the evidence adduced by Applicant in the prosecution of this application, the valuable patent rights covering the Applicant's invention continue to reside with the wrong party who has transferred his rights to a foreign corporation which is actively using the patent rights in derogation of the rightful owners of the subject invention. As a result, the Applicant's position in the commercial marketplace has been severely prejudiced. All the Applicant seeks is to "have his day in court" in order to enable him to regain control over the rights to his invention, before it is too late and the Applicant is depleted of the resources it needs to meet the challenge.

V. CONCLUSION

The Examiner has erred, both in the unauthorized issuance of the March 6, 1995 Office Action, and in the way examination is being conducted in this application. For all of the foregoing reasons, the Applicant respectfully requests that the Group Director exercise his authority by withdrawing the March 6, 1995 Office Action, and pursuant to his review of the record, require the Examiner to (a) allow the pending claims and initiate an interference with the '071 patent; or, in the event this request is not granted, (b) to propose a claim that defines the same invention as the '071 patent and would be patentable to the Applicant; or, in the alternative, in the event this request is not granted, (c) to supply an affidavit pursuant to 37 C.F.R. § 1.107(b) specifying the facts within her personal knowledge, the data being as specific as possible, to support the application of the references cited against the claims.

Such relief is warranted to serve important public interests -- applicants, patent owners and the public must be confident in the PTO's examination of inventions as Congress intended.

Respectfully submitted,

Date: March 16, 1995

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